

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Osamu HONMOU et al.

Title: INTERNALLY ADMINISTERED
THERAPEUTIC AGENTS FOR CRANIAL
NERVE DISEASES COMPRISING
MESENCHYMAL CELLS AS AN ACTIVE
INGREDIENT (As Amended)

Appl. No.: 10/562,202

Filing Date: 6/25/2004

Examiner: Unassigned

Art Unit: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

English abstracts of the foreign-language patent documents are provided. The relevance of each foreign language literature reference is discussed in the specification. The absence of full English translations does not relieve the PTO from its duty to consider the submitted foreign language documents (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

Date April 13, 2006

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5569
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By 

for Stephen B. Maebius *Matthew Mulkeen*
Attorney for Applicant
Registration No. 35,264 *Reg. No. 44,250*

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| | | | | Group Art Unit | Unassigned |
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| Sheet | 1 | of | 11 | Attorney Docket Number | 038873-0108 |

| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| Examiner Initials* | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
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| FOREIGN PATENT DOCUMENTS | | | | | | | | |
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| | | Office ³ | Number ⁴ | Kind Code ⁵ (if known) | | | | |
| | B1 | WO | 03/038075 | A1 | Renomedix Institute Inc. | 05/08/2003 | | |
| | B2 | WO | 02/00849 | A1 | Hokkaido Technology Licensing Office Co., Ltd. | 01/03/2002 | | |

| NON PATENT LITERATURE DOCUMENTS | | | | |
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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ | |
| | B3 | AGGARWAL, <i>et al.</i> , "Human mesenchymal stem cells modulate allogeneic immune cell responses", Blood, Vol. 105, Number 4,. pp. 1815-1822, (2005). | | |
| | B4 | AKIYAMA, <i>et al.</i> , "Transplantation of Clonal Neural Precursor Cells Derived from Adult Human Brain Establishes Functional Peripheral Myelin in the Rat Spinal Cord", Experimental Neurology, Vol. 167, pp. 27-39 (2001). | | |
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| | B7 | BANG, <i>et al.</i> , "Autologous Mesenchymal Stem Cell Transplantation in Stroke Patients", Ann Neurol, Vol. 57, pp. 874-882 (2005). | | |
| | B8 | BARKER, <i>et al.</i> , "Acute Stroke: Evaluation with Serial Proton MR Spectroscopic Imaging", Radiology, Vol. 192, pp. 723-732 (1994). | | |
| | B9 | BEDERSON, <i>et al.</i> , "Evaluation of 2, 3, 5-Triphenyltetrazolium Chloride as a Stain for Detection and Quantification of Experimental Cerebral Infarction in Rats", Stroke, Vol. 17, No. 6, pp. 1304-1308 (1986). | | |
| | B10 | BENDER, <i>et al.</i> , "Identification and Comparison of CD34-Positive Cells and Their Subpopulations From Normal Peripheral Blood and Bone Marrow Using Multicolor Flow Cytometry", Blood, Vol. 77, No. 12, pp. 2591-2596 (1991). | | |

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| | B11 | BERNSTEIN, <i>et al.</i> , "Suppression of Human Cytotoxic T Lymphocyte Responses by Adherent Peripheral Blood Leukocytes", Annals New York Academy of Science, Vol. 532, pp. 206-213 (1988). | | |
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| | B13 | BLAKEMORE, <i>et al.</i> , "Extensive Oligodendrocyte Remyelination following Injection of Cultured Central Nervous System Cells into Demyelinating Lesions in Adult Central Nervous System", Dev. Neurosci., Vol. 10, pp. 1-11 (1988). | | |
| | B14 | WIESEL, <i>et al.</i> , "Remyelination of CNS axons by Schwann cells transplanted from the sciatic nerve", Nature, Vol. 266, p. 68-69, (1977). | | |
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| | B17 | CHEN, <i>et al.</i> , "Therapeutic benefit of intracerebral transplantation of bone marrow stromal cells after cerebral ischemia in rats", Journal of the Neurological Sciences, Vol. 189, pp. 49-57 (2001). | | |
| | B18 | CHOPP, <i>et al.</i> , "Spinal cord injury in rat: treatment with bone marrow stromal cell transplantation", NeuronReport, Vol. 11, No. 13, pp. 3001-3005 (2000). | | |
| | B19 | DESHARI, <i>et al.</i> , "Enhanced antitumor effect of RGD fiber-modified adenovirus for gene therapy of oral cancer", Cancer Gene Therapy, Vol. 10, pp. 75-85 (2003). | | |

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| | B20 | ESCOLAR, <i>et al.</i> , "Transplantation of Umbilical-Cord Blood in Babies with Infantile Krabbe's Disease", The New England Journal of Medicine, pp. 2069-81 (2005). | | |
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| | B23 | FRIEDENSTEIN, A.J., "Precursor Cells of Mechanocytes", International Review of Cytology, 1976, vol. 47, pp. 327-359. | | |
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| | B26 | GOTO, <i>et al.</i> , "GABA Receptor Agonist Promotes Reformation of the Striatonigral Pathway by Transplant Derived from Fetal Striatal Primordia in the Lesioned Striatum", Experimental Neurology, Vol. 147, pp. 503-509 (1997). | | |
| | B27 | GUMPEL, <i>et al.</i> , "Transplantation of Human Embryonic Oligodendrocytes into Shiverer Brain", Annals New York Academy of Sciences, Vol. 495, pp. 70-85 (1987). | | |

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| | B28 | HAMANO, <i>et al.</i> , "Angiogenesis Induced by the Implantation of Self-Bone Marrow Cells: A New Material for Therapeutic Angiogenesis", Cell Transplantation, Vol. 9, pp. 439-443 (2000). | | |
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| | B30 | HIROUCHI et al., "Current state on development of neuroprotective agents for cerebral ischemia," Folia Pharmacol. Jpn., Vol. 120, pp. 107-113 (2002). | | |
| | B31 | HONMA, <i>et al.</i> , Intravenous infusion of immortalized human mesenchymal stem cells protects against injury in a cerebral ischemia model in adult rat", Experimental Neurology, pp. 1-11 (2005). | | |
| | B32 | HONMOU, <i>et al.</i> , "Restoration of Normal Conduction Properties in Demyelinated Spinal Cord Axons in the Adult Rat by Transplantation of Exogenous Schwann Cells", The Journal of Neuroscience, Vol. 16, pp. 3199-3208 (1996). | | |
| | B33 | HUSS, <i>et al.</i> , "Evidence of Peripheral Blood-Derived, Plastic-Adherent CD34 ^{-low} Hematopoietic Stem Cell Clones with Mesenchymal Stem Cell Characteristics", Stem Cells, Vol., 18, pp. 252-260 (2000). | | |
| | B34 | Iihoshi, <i>et al.</i> , "A therapeutic window for intravenous administration of autologous bone marrow after cerebral ischemia in adult rats", Brain Research, Vol. 1007, pp. 1-9 (2004). | | |
| | B35 | IMAIZUMI, <i>et al.</i> , "Transplanted Olfactory Ensheathing Cells Remyelinate and Enhance Axonal Conduction in the Demyelinated Dorsal Columns of the Rat Spinal Cord", The Journal of Neuroscience, Vol. 18, pp. 6176-6185 (1998). | | |

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| | B36 | INOUE et al., "Comparative Analysis of Remyelinating Potential of Focal and Intravenous Administration of Autologous Bone Marrow Cells Into the Rat Demyelinated Spinal Cord," GLIA, 2003, pp. 111-118, Vol. 44. | | |
| | B37 | IWADATE et al., "Induction of Immunity in Peripheral Tissues Combined with Intracerebral Transplantation of Interleukin-2-producing Cells Eliminates Established Brain Tumors," Cancer Research, Dec. 15, 2001, pp. 8769-8774, Vol. 61. | | |
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| | B44 | KOÇ et al., "Rapid Hematopoietic Recovery After Coinfusion of Autologous-Blood Stem Cells and Culture-Expanded Marrow Mesenchymal Stem Cells in Advanced Breast Cancer Patients Receiving High-dose Chemotherapy," J. Clin. Oncol., 2000, pp. 307-316, Vol. 18, No. 2. | | |
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| | B48 | LONGA et al., "Reversible Middle Cerebral Artery Occlusion Without Craniectomy in Rats," Stroke, January 1989, vol. 20, no. 1, pp. 84-91. | | |
| | B49 | MAJUMDAR et al., "Phenotypic and Functional Comparison of Cultures of Marrow-Derived Mesenchymal Stem Cells (MSCs) and Stromal Cells," J. Cell. Physiol., 1998, pp. 57-66, Vol. 176. | | |
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| | B51 | R. MORRIS, "Spatial Localization Does Not Require the Presence of Local Cues," Learning and Motivation, 1981, pp. 239-260, Vol. 12. | | |

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| | | | | Group Art Unit | Unassigned |
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